510(k) SUMMARY

MAR 2 1 2012

Upstream Peripheral Technologies Needle Holder—K112887

Applicant Information:

Upstream Peripheral Technologies, Ltd.
ARAN Building
P.O. Box 3067
43 Haeshel Street
Caesarea 38900
Israel

Phone: (972) 4-6239014
Facsimile: (972) 4-6273260
Contact Person: Dan Rottenberg
Date Prepared: March 21, 2012

Device Information:

Trade Name:	Upstream Needle Holder, Upstream Needle Holder with shut-off connector
Common or Usual Name:	Introducer Catheter
Classification:	Class II per 21 CFR 870.1340
Product Code:	DYB
Predicate Device:	BD Introsyte Precision Introducer (K013304)

Intended Use / Indications for Use:

The Upstream Needle Holder is intended to facilitate the placement of guidewires into the vascular system.

Technological Characteristics:

The Upstream Needle Holder is a sterile, single-use, single lumen rigid polymer tube having male luer connector at the distal end to provide connection to standard needle, and female luer connectors at the proximal end for guidewire access. The Upstream Needle Holder with shut-off connector includes a standard shut-off connector. The shut-off connector includes a sliding element that opens and closes the connector lumen.

The Upstream Needle Holder is intended for use with guidewires of up to 0.0315" diameter. The Upstream Needle Holder is provided in a 23 cm length. The hub at distal end of the Upstream Needle Holder interfaces with a standard needle connection. The hub at the proximal end of the Upstream Needle Holder allows guidewire access, or connection of shut-off connector through which a guidewire is inserted and may be locked in position using the connector lock position.

Safety and Performance Data:

The Upstream Needle Holder has been evaluated for biocompatibility in accordance with ISO 10993 to ensure that the materials used in the manufacturing of the device are biocompatible. The biocompatibility tests performed included the following:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Hemolysis
- Partial Thromboplastin Time
- Platelet and Leukocyte Counts
- Complement Activation Testing

Additionally, the following in vitro bench testing has been performed:

- Tensile Strength
- Air Leakage
- Liquid Leakage Under Pressure
- Surface Test
- Needle Holder Dimensions
- Guidewire Capture and Passage Test
- Hub Testing
- Environmental Packaging Testing
- Endotoxin Testing
- Sterilization and Shelf-Life Validation Testing

All of these tests demonstrated that the Upstream Needle Holder meets its intended performance specifications.

Substantial Equivalence:

The Upstream Needle Holder and the predicate device have the same intended use and very similar indications, technological characteristics, and principles of operation. The minor technological differences between the Upstream Needle Holder and its predicate device raise no new types of safety or effectiveness questions. In vitro verification testing demonstrates that the Upstream Needle Holder performs as intended and meets all design specifications with respect to

their mechanical and handling characteristics, and that its materials are biocompatible. Thus, the Upstream Needle Holder is substantially equivalent to the BD Introsyte Precision Introducer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Upstream Peripheral Technologies, Ltd.
c/o Ms. Janice Hogan
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, PA 19103

MAR 2 1 2012

Re: K112887
Trade/Device Name: Upstream Needle Holder, Upstream Needle Holder with shut-off connector
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: February 14, 2012
Received: February 14, 2012

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): **K112887**

Device Name: Upstream Needle Holder, Upstream Needle Holder with Shut-Off Connector

Indications for Use:

The Upstream Needle Holders are intended to facilitate the placement of guidewires into the vascular system.

Prescription Use _____X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hollebeck

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112887